

REMARKS

Claims 1-37 are pending in this application. Claims 5, 12-17, and 22-31 are withdrawn from consideration, Claims 1-4, 6-11, 18-21, and 32-37 have been examined. Claims 1, 2, 6-9, 18-21, 32, and 35-37 stand rejected. The Examiner's indication that Claims 3, 4, 10, 11, 33, and 34 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims is noted with appreciation. Reconsideration and allowance of Claims 1-37 is respectfully requested.

The Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1, 2, 4, 6-9, 18-21, 32, and 34-37 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,368,794 (Daniel et al.). Applicant respectfully disagrees.

According to the Examiner, applicant has failed to distinguish the Daniel et al. analytes from those in the claimed invention. Applicant respectfully submits that an "analyte of previously uncharacterized specific pharmacological activity" in step (c) of the claimed methods refers to an analyte that has not been characterized for specific pharmacological activity relevant to the known parameter of step (b) of the claimed methods. This is described in the specification as follows:

Another difference between the method of this invention and past practices is that the method of the invention encompasses the screening of compounds with no previously known pharmacological action, in order to identify drug candidates by virtue of molecular expression profile. Also, the method encompasses the screening of compounds with a specific known drug action, in order to identify different, novel drug action of potential pharmacological utility in other pathologies (Specification, page 14, lines 19-24).

The present invention provides a method for deriving such molecular expression profiles when followed by characterization of and comparison with the molecular expression profiles of similar samples treated with analytes that are unknown to have an effect on the specific state represented by the molecular expression profile, in order to evaluate

whether those analytes exert a desirable or other specific effect on molecular expression profiles of relevant tissue (Specification, page 8, line 27, to page 9, line 3).

These passages clarify that the phrase "analyte of previously uncharacterized specific pharmacological activity" encompasses (1) analytes that have never been characterized for any pharmacological activity, and (2) analytes that have not been characterized with respect to the specific pharmacological activity relevant to the expression profiles of the first and second biological samples that differ from each other by a known parameter (steps (a) and (b) of the claimed method).

The specification further clarifies that the phrase "analyte of previously uncharacterized specific pharmacological activity" does not encompass established drug candidates. For example, the specification states:

Previously uncharacterized chemicals that exhibit a specific biochemical activity revealed by the screen are reclassified as "candidate drugs", also known as "hits", "drug candidates" and "drug leads". Such newly-identified candidate drugs subsequently proceed through the drug development pipeline which includes the process of "triage", where candidate drugs are subjected to further characterization and analysis to rank the candidates in order of likely efficacy and toxicity (Specification, page 2, lines 19-25).

The method of the invention does not include the screening of compounds with previous biochemically-derived evidence of specific utility (i.e. established drug candidates), in order to identify toxicological molecular expression profiles (see, e.g., Rothberg et al., 2000). Nor does the method of the invention include the screening of established drug candidates, in order to more fully characterize the utility for which they have already been indicated (Specification, page 14, lines 19-30).

Daniel et al. neither discloses nor suggests a treatment with an analyte of previously uncharacterized specific pharmacological activity, as recited in step (c) of the claimed invention. Instead, the only analytes and the only treatments disclosed or suggested in Daniel et al. are therapeutic agents and therapeutic treatments (Daniel et al., Col. 1, lines 37-38 and 62-65; Col. 11, line 59, to Column 14, line 15). Therefore, Daniel et al. neither discloses nor suggests a treatment with an analyte of previously uncharacterized specific pharmacological activity, as recited in step (c) of the claimed invention.

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Moreover, Daniel et al. only describes using assays "to evaluate the efficacy of a particular therapeutic treatment regimen in animal studies, in clinical trials, or to monitor the treatment of an individual patient" (Col. 10, lines 64-67) or to "develop and monitor the activities of therapeutic agents" (Daniel et al., Col. 11, lines 12-18). Therefore, Daniel et al. neither discloses nor suggests a method to "identify one or more analytes that induces a third expression profile that is more similar to the first expression profile than is the second expression profile" from analytes of previously uncharacterized specific pharmacological activity, as recited in step (d) of the claimed invention.

For all the reasons above and the reasons already of record, applicant submits that Daniel et al. does not suggest or provide any motivation to arrive at the claimed invention and respectfully requests withdrawal of this ground of rejection.

Examination of Non-Elected Species

In the election requirement mailed September 22, 2003, Claims 1-4, 6-8, and 18-21 were found to be generic. The species "polynucleic acid microarrays" was elected for initial examination. Applicant respectfully submits that the pending claims are allowable with respect to polynucleic acid microarrays and request rejoinder of the claims that have been withdrawn and examination of the other species in the genus.

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Conclusion

In view of the foregoing amendments and remarks, the application is believed to be in condition for allowance. If any issues remain that can be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicant's attorney at 206.695.1783.

Respectfully submitted,

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Date:

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